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Mohamed Ahmed Shaban Elghanam

assistant lecture of cardiothoracic surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt,
melghanam1989@gmail.com

El-Husseiny El-Husseiny Gamil

Professor of cardiothoracic surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Mohammed Eldesoky Sharaa

Professor of cardiothoracic surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Haythm Mohamed Abd ElMoaty

Lecture of cardiothoracic surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

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Early Results of Surgical Intervention in Patients with Malfunction Prosthetic Cardiac Valves

Mohamed Ahmed Shaban Elghanam*, El-Husseiny El-Husseiny Gamil, Mohammed Eldesoky Sharaa, Haythm Mohamed Abd ElMoaty

Department of Cardiothoracic Surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt

Abstract

Background: After their insertion, prosthetic valves—either mechanical or biological—have some drawbacks. There are many challenging events that lead to dysfunction of prosthesis, such as formation of a thrombus or pannus, para-valvular leakage, and developing cardiac infections after the prosthesis, like endocarditis.

Objective: To assess factors that are responsible for malfunction of prosthetic cardiac valves; in addition, assessment of post-operative mortality and morbidity of those patients.

Patient and methods: In this prospective study, we followed-up the early results of surgical intervention in 40 patients with malfunction prosthetic cardiac valves at the Cardiothoracic Surgery Department, El-Hussien Hospital, Al-Azhar University; the follow-up timespan was from March 2019 to May 2022.

Results: The study reported the causative events of prosthetic valves malfunction as the following: Thrombus formation was reported in 25% of the total patients included in the study, while thrombus and pannus were reported in 37.5%. Pannus only was reported in 30% of the total patients included in the study. The calculated overall mortality for patients who suffered from prosthesis' malfunction, which mandated-replacement of valve, was 7 out of 40 patients (17.5%).

Conclusion: This study concluded that the major complication that leads to failure of mechanical valve prosthesis is formation of both thrombus and pannus; surgical management is associated with significant mortality and morbidity. Hence, better clinical outcomes can be achieved by both early diagnosis and prompt reoperation.

Keywords: Heart, Malfunction, Prosthesis

1. Introduction

Around 100 million people around the world are suffering from diseases related cardiac valves, which lead to substantial morbidity and mortality.¹ Malfunctioning of the prosthetic valves can happen as consequence after placement of either mechanical or biological valves. This can take several forms as the following: decrease in the leaflet movement, increase in the thickness of the leaflet, disturbance in the effective prosthesis orifice area (either stenosis or insufficiency), and valvular regurgitation; sometimes these events can trigger symptoms but they may be asymptomatic.² Following either surgical or transcatheter valve replacement, the dose and duration of

antithrombotic therapy can be determined by the prosthetic valve type, and the patient's evaluated risk of bleeding and thrombo embolism.³ Failure of a prosthetic valve is a potentially fatal problem that needs to be dealt with immediately. Accordingly, identifying the source of the malfunctioning prosthetic valve is essential for deciding which action should be taken. Thrombotic events on top the prosthesis can be managed with either by surgical intervention, thrombolysis, and anticoagulation therapies.⁴ Patients known to have a prosthetic valve placement and complain of acute dyspnea or an embolic event must be investigated immediately for obstructive valve thrombosis. If accessible, a computed tomography (CT) scan, cinefluoroscopy, TTE, and TOE should be used to promptly confirm

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* Corresponding author at: Cardiothoracic Surgery, Faculty of Medicine, Al-Azhar University, Nasr City, Cairo 11884, Egypt. Fax: +20224020184. E-mail address: melghanam1989@gmail.com (M.A.S. Elghanam).

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the diagnosis.⁵ Regardless of the chosen management option, the care of mechanical prosthetic valve thrombosis carries a considerable risk. For example, surgery is considered to be a high-risk option since it is frequently carried out in an emergency situation; in addition, it is considered as a re-intervention. Meanwhile, fibrinolysis also involves considerable risks of hemorrhage, spread of emboli systemically, and recurring thrombosis which occurred more frequently compared with surgical option.⁶ Urgent interfering with either fibrinolytic therapy (slow infusion and low-dose initially) or emergency surgical intervention is life-saving for patients with a placed left-sided mechanical prosthesis who develop symptoms that indicates valve blockage by a thrombus.⁷

2. Patients and methods

In this Prospective study, we followed-up the early results of surgical intervention in 40 patients with prosthetic cardiac valves' malfunction at the Cardiothoracic Surgery Department, Elhussien Hospital, Al-Azhar University; the follow-up time span was from March 2019 to May 2022. Hence, the study included patients with prosthetic cardiac valves' malfunctions. There are many challenging events that lead to dysfunction of prosthesis, such as formation of a thrombus or pannus, para-valvular leakage, and developing cardiac infections after the prosthesis, like endocarditis; as a result, these can cause significant valve stenosis or regurgitation. In this study, we excluded patients who underwent any other surgical cardiac intervention rather than prosthetic mechanical valve re-replacement; for example, people with previously performed CABG due to ischemic heart disease. Also, patients with identified chronic liver diseases, identified chronic kidney diseases, and known parenchymal pulmonary diseases were excluded. All patients were subjected to preoperative thorough assessment and history taking by reporting detailed medical history. Appropriate analysis of all symptoms was performed. It should also be noted that the severity of symptoms in these patients had a very wide spectrum; it ranged from mild symptoms to cardiogenic shock with very bad general condition. However, some of our patients sought intervention based Onan echocardiographic evidence of valve dysfunction while they were completely asymptomatic. Clinical examination: A thorough clinical examination was performed by reviewing of the approach of the operation (sternotomy or thoracotomy). Heart rate was evaluated carefully to exclude new-onset tachycardia that may indicate potential

valve problem, heart failure, or fever in PVE. Blood pressure was also checked to exclude any decrease that may indicate cardiogenic shock. Also, patients were checked for any temperature abnormality, edema in lower limbs, urinary output, or having any abnormal decubitus. Furthermore, auscultation of prosthetic valve and chest was carried out to search for metallic sound, murmur, or bilateral for basal crepitation, respectively. Laboratory workup: Complete blood picture (CBC), erythrocyte sedimentation rate (ESR), LFT, KFT, and coagulation profile were obtained. Diagnostic cardiac investigation: Electrocardiography (ECG), radiography on chest were obtained to evaluate the chest condition, number of stainless-steel wires of prior sternotomy, and heart-sternum relation. *Trans*-thoracic Echocardiography was done to evaluate leaflet motion, thrombotic existence, vegetations, para-valvular leakage, valve dehiscence, pulmonary artery pressure, chambers' dimensions estimation, and ejection fraction. *Trans*-esophageal Echocardiography (TEE) was used for describing detailed cardiac anatomy and pathology; whenever needed, Fluoroscopy was employed when there was any borderline finding on TEE, and in any patient with high clinical suspicion of malfunction. Moreover, diagnostic coronary angiography was employed electively in patients older than 40 years, in order to exclude their need of CABG. Intraoperative assessment: All steps were performed while the patient was supine and under general anesthesia, utilizing an oscillating saw to cut through the median sternum after exposing the femoral artery and vein for potential use. Heart was manipulated by gentle dissection over the right atrium, leaving the left side undissected, unless needed, to avoid bleeding from exposed raw surface. Then, we had dissected the sternum from the heart with the diathermy to reduce the incidence of post operative bleeding; meanwhile, we were dissecting the heart using sharp dissection by the scissors to avoid arrhythmias from the diathermy. The left pleura had been opened to mobilize apex of the heart. Full dose heparin (300 unit/kg) was given to all participants. After cannulas had been placed, cardio-pulmonary bypass was then started. The aorta should be cross-clamped; then an antegrade infusion of cold blood cardioplegia solution intermittently had been applied to preserve the myocardium with achieving systemic hypothermia to 28 °C. Topical ice was applied to obtain cooler temperature. As those patients were usually overloaded, we were used to do ultra-filtration for those patients with accurate calculation of the patient's balance during the operation cautiously in order to avoid renal shutdown. After an access to the valve

was obtained, assessment of the valve was then done to reach to the optimal diagnosis. Following the gentle removal of the valve, debridement is done for the native ring. Then the valve was evaluated for size to get the ideal one for the new prosthetic valve. Then, introduction of the new prosthesis using interrupted transverse mattress 2/0 ethibond sutures with Teflon pledges was completed. Rewarming, debubbling, and cross-clamp removal were taking place followed by cardiopulmonary bypass weaning. Hemostasis was ensured cautiously with usage of protamine 1 mg to every 100 unite of heparin used, and usage fresh frozen plasma. Closure in layers had been done over drainage tubes (2 retrosternal, one in the left pleura and the other in right pleura, if needed) and ventricular pacemaker wires. Discharge to the ICU was done. Postoperative assessment: ICU data and medications, including the need for inotropic support: After patients had been transferred to I.C.U. successfully, they were monitored continuously for the following: arterial pressure using arterial cannula, central venous pressure using internal jugular venous line, and Foley's catheter to monitor the urinary output. Negative balance was planned in the first day post operative through diuresis with the insurance of good tissue perfusion. As regard to chest tube drainage, the amount of drainage was monitored hourly and patients were ventilated postoperatively until they became fully conscious and hemodynamically stable with accepted amount of drainage. Then they were discharged to the ward to be prepared for hospital discharge. Postoperatively, if no signs of ongoing bleeding were seen, all patients were prescribed warfarin as anti-coagulant for life. Within the early postoperative days, we used heparin along with warfarin till the estimated INR was below 2. The INR was maintained between 2.5 and 3.5 in all patients with prosthetic mitral valve and between 2 and 3 in all patients with prosthetic aorta. Any signs of postoperative complications were carefully observed especially bleeding, stroke, chest infection, renal failure, wound infection, mortality, and the need for re-exploration. Early postoperative observed results included echocardiography data before discharge as well as checking for the need for medical treatment or further hospital stay. Echocardiography was planned one month postoperatively.

3. Results

This study was conducted on 40 patients having malfunction prosthetic cardiac valves who underwent re-replacement of the valve prosthesis. The

age of the participants ranged from 19 to 62 years at the time of surgical intervention. The mean age was 34.87 ± 9.83 years. There were 12 males (30%) and 28 females (70%).

Preoperative factors associated with mortality: the overall mortality rate was 17.5% (7 patients). We have conducted further investigations to clarify variables that are correlated with mortality; the following preoperative factors have been reported to be significantly correlated with mortality: mean arterial blood pressure below 70 mmHg ($P = 0.047$), tachycardia above 100/minutes ($P = 0.019$), acute pulmonary edema ($P = 0.019$), need for preoperative mechanical ventilation ($P = 0.019$), cerebro-vascular stroke ($P = 0.03$), disturbance of conscious level ($P = 0.028$), kidney insufficiency ($P = 0.03$), and low EF ($P = 0.015$). There was no significant relationship between mortality and the age ($P = 0.395$), sex ($P = 0.286$), NYHA class ($P = 0.073$), presence of LL edema ($P = 0.448$), liver dysfunction ($P = 0.552$), diabetes mellitus ($P = 0.448$), INR level ($P = 0.236$), AF ($P = 0.105$), previous more than one open heart surgery ($P = 0.448$), time to admission to the OR ($P = 0.195$), SPAP ($P = 0.052$), elevated pressure gradient across the valve ($P = 0.448$), immobile leaflet in the echo ($P = 0.448$), detected thrombus in the echo ($P = 0.286$) or paravalvular leak ($P = 0.552$) [Table 1](#).

Moreover, there was a strong positive correlation reported between mortality and the following: longer cross-clamp time ($P = 0.005$), longer cardiopulmonary bypass time ($P = 0.001$), and the need for higher inotropic support after weaning from bypass ($P = 0.002$). There was no significant relationship between mortality and detection of thrombus on the prosthetic mitral valve during surgery ($P = 0.259$) or detection of pannus ($P = 0.569$) [Table 2](#).

As regard to the postoperative variables, we found that there was a strong positive correlation between mortality and the following: longer postoperative mechanical ventilation time ($P = 0.001$), kidneys' failure ($P = 0.001$), stroke ($P = 0.026$), chest infection ($P = 0.016$), and wound infection ($P = 0.009$). There was no significant relationship between mortality and need for re-exploration ($P = 0.224$) [Table 3](#).

4. Discussion

This work included 40 patients with either of the following: malfunctioning prosthetic valves, thrombosis on top of the valve prosthesis, or the need re-replacement of the valve prosthesis. In our study, the age of the patients ranged from 19 to 62 years at the time of surgical intervention. The mean age was 34.87 ± 9.83 years, with 77.5% of our patients aging

Table 1. Preoperative factors associated with mortality.

Peroperative Factor	Mortality number (%)	P value
Age:		
Died	38.9 ± 16.3	0.395
Discharged	35.2 ± 8.7	
Sex		
Female	4/28 (14.3%)	0.286
Male	3/12 (25%)	
NYHA class:		
III	0/12 (0%)	0.073
IV	7/28 (25%)	
Mean ABP:		
<70 mm Hg	4/11 (36.4%)	0.047*
≥70 mm Hg	3/29 (10.3%)	
Heart rate/min:		
> 100	7/24 (29.2%)	0.019*
≤100	0/16 (0%)	
Acute pulmonary edema:		
Present:	4/4 (100%)	0.019*
Absent:	3/36 (8.33%)	
Need for mechanical ventilation:		
Present:	4/4 (100%)	0.019*
Absent:	3/36 (8.33%)	
LL edema:		
Present:	1/3 (33.3%)	0.448
Absent:	6/37 (16.2%)	
Cerebrovascular stroke:		
Present:	3/5 (60%)	0.03*
Absent:	4/35 (11.4%)	
Disturbed conscious level:		
Present:	1/1 (100%)	0.028*
Absent:	6/39 (15.4%)	
Renal dysfunction:		
Present:	3/5 (60%)	0.03*
Absent:	4/35 (11.4%)	
Liver dysfunction:		
Present:	1/4 (25%)	0.552
Absent:	6/36 (16.7%)	
Diabetes mellitus:		
Present:	1/3 (33.3%)	0.448
Absent:	6/37 (16.2%)	
INR level:		
< 2	4/30 (13.3%)	0.236
≥ 2	3/10 (30%)	
AF:		
Present:	6/23 (26.1%)	0.105
Absent:	1/17 (5.9%)	
Previous open-heart surgery:		
1	5/35 (14.2%)	0.448
>1	2/5 (40%)	
Time to admission to the OR:		
≤24 h	3/25 (12%)	0.195
> 24 h	4/15 (26.6%)	
EF:		
< 50	3/4 (75%)	0.015*
≥ 50	4/36 (11.1%)	
SPAP:		
≤ 60	7/25 (28%)	0.052
> 60	0/15 (0%)	
Elevated pressure gradient in the Echo:		
Present:	7/36 (19.4%)	0.448
Absent:	0/4 (0%)	

(continued on next page)

Table 1. (continued)

Peroperative Factor	Mortality number (%)	P value
Immobile leaflet in the Echo:		
Present:	7/36 (19.4%)	0.448
Absent:	0/4 (0%)	
Detected thrombus in the Echo:		
Present:	3/12 (25%)	0.286
Absent:	4/28 (14.3%)	
Paravalvular leak:		
Present:	0/3 (0%)	0.552
Absent:	7/37 (18.9%)	

less than or equal to 40 years. Our findings are different from those reported by Potter and colleagues study; they studied 106 patients whom mitral valves were replaced repeatedly within the period from January 1993 to December 2000 at Mayo Clinic, Minnesota, USA; their sample mean age was 66 ± 12 . Another research work from Southampton University Hospitals, UK carried out by Vohra and colleagues, they investigated the results of 49 participant underwent redo mitral valve replacement within the period from Jan 2000 to 2010; their sample mean age was 63 ± 13 years (range 21–80 years).^{8,9} In Egypt, the most frequently identified disease leading to heart valve replacement is rheumatic heart disease, that is mostly prevalent in younger age groups. Meanwhile, in other counties like USA and UK, the most frequently identified trigger of valvular replacement is degenerative heart valve diseases, that is mostly prevalent in older age groups. This explains why there was a notable variability in the mean age among our participants and these studies' participants. Our patients were 12 males (30%) and 28 females (70%). This distributive pattern of sex is comparable to many other investigations, like Ahn and colleagues¹⁰ study which included 20 patients with thrombotic mechanical valve who were admitted for

Table 2. Intraoperative variables related to mortality.

Intraoperative Factors	Mortality number (%)	P value
Cross clamp time:		
≤ 90	1/27 (3.7%)	0.005*
> 90	6/13 (46.15%)	
Cardiopulmonary bypass time:		
≤ 120	0/25 (0%)	0.001*
> 120	7/15 (46.6%)	
Thrombus on the prosthetic valve:		
Present:	7/25 (28%)	0.259
Absent:	0/15 (0%)	
Pannus on the prosthetic valve:		
Present:	3/27 (11.1%)	0.569
Absent:	4/13 (30.7%)	
Weaning from bypass:		
High inotropic support	7/12 (58.3%)	0.002*
Low inotropic support	0/28 (0%)	

Table 3. Postoperative variables related to mortality.

Postoperative Factors	Mortality number (%)	P value
Duration of mechanical ventilation ^b :		
Died	206.5 ± 102.8	0.001 ^a
Discharged	15.1 ± 14	
Need for re-exploration ^a :		
Yes	2/6 (33.3%)	0.224
No	4/33 (12.1%)	
Renal failure ^b :		
Present:	4/5 (80%)	0.001 ^a
Absent:	0/32 (0%)	
Stroke ^b :		
Present:	2/3 (66.7%)	0.026 ^a
Absent:	2/34 (5.9%)	
Chest infection ^b :		
Present:	3/7 (42.9%)	0.016 ^a
Absent:	1/30 (3.3%)	
Wound infection ^b :		
Present:	2/2 (100%)	0.009 ^a
Absent:	2/35 (5.7%)	

^a Intraoperative death = 1 patient.

^b Death intraoperative or early in the ICU = 3 patients.

surgical management from January 1981 to March 2006 in Seoul National University Hospital, Korea; 70% of their study's participants were females and 30% were males. Nevertheless, Ghoreishi and colleagues¹¹ included 130 patients who re-underwent sternotomy for mitral valve operations between January 2004 and June 2012 at University of Maryland School of Medicine, USA; 45% of their patients were females and 55% were males. This contrasted with our study's sex distribution, as the females were more liable to malfunctioning of the valve than males. Our work showed an overall mortality of 7 out of 40 patients (17.5%). This conforms with the results of Raboi and colleagues¹² who reported 17.8% overall mortality. Our mortality rate was higher than other work like those by Brik and colleagues who reported 3.3%, Ghoreishi and colleagues 4.6%, and Vohra and colleagues 12%.^{9,11,13} With further analysis, we reported a strong correlation between mortality and some preoperative variables as the following: low mean arterial blood pressure (below 70 mmHg), tachycardia (above 100/minutes), acute pulmonary edema, needed preoperative mechanical ventilation, cerebro-vascular stroke, disturbance in conscious level, kidney insufficiency, and decreased EF. Moreover, our study shows a strong positive correlation between mortality and the following: longer cross-clamp time, longer cardio-pulmonary bypass time, and the need for higher inotropic support after weaning from bypass, postoperative mechanical ventilation time, postoperative kidneys' failure, stroke, postoperative chest infections, and postoperative wound infections. On the other hand, Akay and

colleagues¹⁴ demonstrated that the following are risk factors for mortality: NYHA functional class IV, decreased left ventricular EF (<35%), female gender, pulmonary edema, and urgent operations. Additionally, in Ozyazöcöoglu and colleagues study, they showed that emergency surgery, infective endocarditis, valvular sticking, and infections were related to early mortality. Unlike Toker and colleagues results which depicted that the only variable that affects early hospital mortality is left ventricular EF.^{15,16}

4.1. Conclusion

This study came to the conclusion that pannus and thrombosis are the two key players in mechanical valve prostheses malfunctioning, and that surgical intervention is linked to considerable morbidity and mortality. For improved clinical results, earlier detection and immediate re-operation are essential. Given the significant rate of thrombosis in this series, it is imperative that patients get appropriate anticoagulation and ongoing monitoring following first mechanical valve replacement.

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Authorship

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Conflicts of interest

The authors declared that there were NO conflicts of Interest.

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